

HN (NI) 2002/08

DATE: 23 October 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**INVACARE LTD – ZIPPER 2 S MANUAL
WHEELCHAIR – RISK OF PROPELLING
WHEELS BECOMING DETACHED IN USE**

MANUFACTURER/SUPPLIER

Invacare Ltd

PROBLEM

There have been a number of instances of wheels on Zipper 2 S wheelchairs (self propelled model) becoming detached due to the fracture of a die-cast wheel mounting block. If detachment occurs when the wheelchair is in use, the user and/or carer could sustain injury as the wheelchair tips.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Estate Managers
- Wheelchair Service Managers
- Wheelchair Repair and Reconditioning Services
- General Medical Practitioners
- Community and Social Care Staff
- Occupational Therapists (involved in wheelchair provision)
- Physiotherapists (involved in wheelchair provision)
- Residential and Nursing Homes
- Hospices
- Private Clinics
- Library and Education Boards

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

Trace all Invacare Zipper 2 S wheelchairs delivered between 1 April 2002 and 11 June 2002 with serial numbers in the range: GB12090100 to GB32028945. Arrange for the wheel mounting blocks to be replaced as soon as possible in accordance with the manufacturer's instructions – see manufacturer letter at appendix A. (Note: The dates and serial numbers initially quoted in the manufacturer letter were incorrect and have been updated in Annex A).

**HAZARD
NOTICE**



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BACKGROUND

Reports have been received by the Medical Devices Agency (MDA) and Invacare of instances in which the propelling wheel of the Zipper 2 S wheelchair (self propelled model) has completely broken away from the wheelchair. These have occurred as a result of the fracture of a die-cast wheel mounting block. The mounting block, which is bolted to the sideframe, fractures across the rear mounting holes, adjacent to the spindle attachment, allowing the wheel assembly to detach when load is applied to the wheelchair.

Note: Only the Zipper 2 S wheelchairs (self propelled model) are affected: other variants use a different wheel and mounting.

The majority of the incidents reported were noticed after the wheelchair had been transported, folded, in a vehicle before the user actually sat in the wheelchair. However there have been a small number of incidents in which the wheel detached whilst the user was seated in the wheelchair. Injuries were narrowly avoided in these instances.

Because there is a potential for injury if the wheel of the wheelchair suddenly detaches, the manufacturer has written to all customers advising of the need for urgent action. The options available to customers are covered in the manufacturer letter (see appendix) and consist of replacing the block with either a plastic mounting block or a CNC machined mounting block. There will also be a reimbursement of fitting costs of £35.00 for each wheelchair repaired.

The initial ranges of dates and serial numbers circulated by Invacare were incorrect. These have now been revised and are shown in the "Immediate Action" section of this notice and also in Annex A.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Kevin Humphries
Director of Technical Services
Invacare Ltd
South Road
Bridgend Industrial Estate
Bridgend
Mid Glamorgan
CF31 3PY

Tel: 01656 753270

Fax: 01656 649016

Enquires to the NIAIC should quote the reference number HN(NI) 2002/08 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US.

Tel: 02890 523714, Fax: 02890 523900, Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Aisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



26 September, 2002

Customer Name

Dear

Re: Zipper 2 S Alloy Wheel Mounting Blocks.
Date range 1.4.2002 to 11.6.2002
Serial number range GB12090100 to GB32028945

Further to our previous communication regarding the above alloy block, there have been two further reports of fractures that have taken place with the wheelchair in use.

Therefore, as a matter of urgency, Invacare would like to propose replacing the alloy blocks that have been fitted to Zipper 2 S wheelchairs, which had been manufactured during above dates.

The attachment details the number of wheelchairs that have been supplied to you, together with your order details.

We can offer you the following options to swap the existing blocks: -

- Exchange for plastic. The 36-spoke hole wheel will improve the performance of these blocks. The part number for this option is **1426161**
- Exchange for CNC machined blocks. The part number for this option is **1426162**

Will you please advise the delivery address and me of the option you would prefer?

Invacare will compensate you a sum of £35.00 for each chair repaired. Please address your invoice for my attention, quoting the serial number of the wheelchair repaired.

The design of Zipper 2 S wheel mounting block which was fitted to above wheelchairs, did pass the ISO 7176 pt 8 test, the carousel test and compression tests.

Finally I would like to apologise on behalf of Invacare for the inconvenience caused.

I look forward to your instructions.

Yours truly

Kevin Humphries
After Sales and Spares Director

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